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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/092,919	03/08/2002	Kjell Olmarker	003300-914	1488

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EXAMINER	
MONDESI, ROBERT B	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 07/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/092,919	OLMARKER, KJELL	
	Examiner	Art Unit	
	Robert B. Mondesi	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 May 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *11-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 23-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

S.00

DETAILED ACTION

This Office action is in response to the amendment filed May 03, 2005. **Claims 1-10 and 23-25** are presently under examination.

Priority

The current application filed on March 08, 2002 claims priority to foreign application, SWEDEN 0200667-7 filed on March 05, 2002. A certified translation of foreign document SWEDEN 0200667-7 has been provided.

This application contains **claims 11-22** drawn to an invention nonelected with traverse in Paper filed September 08, 2004. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Withdrawal of Objections and Rejections

The objections and rejections not explicitly restated below are withdrawn.

Maintenance of rejections

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 1-10 and 23-25 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in

the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

This rejection was explained in the previous Office action.

Claim Rejections - 35 USC § 102

Claims 1-10 and 23-25 remain rejected under 35 U.S.C. 102(e) as being anticipated by Reuben et al. United States Patent Application Publication US 2002/0072596.

This rejection was explained in the previous Office action.

Response to applicant's arguments

In regards to the rejection of **claims 1-10 and 23-25** under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, the applicants assert that in the context of the present application "prevention" refers to the administration of a substance at the time of injury in order to eliminate the possibility of scare tissue and the unwanted event prevented by the claimed method is the development of scar tissue or other intra spine surgery.

Applicants assert further that the formation of the present invention is a pathologic condition, which often occurs following spinal surgery. Such a scare is organized and fribiotic and compresses the adjacent nerves, producing pain. This condition is also referred as "epidural scarring" or "fibrosis". Thus, the applicants note that the scare tissue of the present invention is different from the scars, which are the normal result of skin and muscle healing, and in fact, the preventative effects of the present methods are similar to the reductive effects.

Applicants also submit that, in the example of the present specification, it is disclosed that the rats treated with a substance according to the claimed methods (infliximab), developed only soft connective tissue rather than developing a "dense lump" as in control rats.

Applicants' arguments have not been found persuasive. The phrase "prevention" is well known term of art, even though the applicants are allowed to be their lexicographer a new definition of an already well known term of art does not remedy the deficiencies with regards to the method of invention in view of prevention. Furthermore, it must be noted that the applicants have provided arguments that are not based on the limitations of the rejected claims but rather are only taught in the specification, for example the applicants discuss the formation of soft connective tissue rather than "dense lump" in rats. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The applicants urge further that the notion of wounds envisioned by the present application is different from the scars which are the normal result of skin and muscle healing; however in response the examiner must indicate that the breadth and language of the claim is not indicative of the stated difference and such indication is only provided for in the specification. The applicants are more than welcome to clarify the reading of the claims by amending the claims in order to further clarify their notion of commonly understood term "scar tissue".

The examiner must also point out that the applicants' statement that "the preventative effects of the present methods are similar to the reductive effects" creates confusion and ambiguity with regards to the method of the invention. Prevention is absolute and complete and therefore it is not possible to partially prevent, either something has been prevented or not. The concept of reduction is indicative of a dosage dependent treatment and that is why the applicants' statement does not provide further clarity or a convincing argument in view of "reductive prevention".

Finally, it must be noted that all the applicants' experimentation and evidence is in light of animal studies, although informative, such experimentation is not indicative of prevention in humans. If the applicants are administering compounds to "patients" in hopes of prevention then it is essential that the applicants provide human models and experiments wherein prevention has been demonstrated in subject humans.

In view of the rejection of **claims 1-10 and 23-25** under 35 U.S.C. 102(e) as being anticipated by Reuben et al., the applicants state that Reuben discloses transferrin sequences, two of which (SEQ ID NO:4 and SEQ ID NO:6) can be derived from the lactoferrin molecule; however, Reuben does not disclose sequences with complete lactoferrin sequence homology. The protein chain of human lactoferrin is folded into two globular lobes, the so-called N- and C-terminal lobes. SEQ ID NO 4 and SEQ ID NO 6, as disclosed in Reuben, appear to resemble lactoferrin sequences belonging to the C-lobe. In contrast, the present invention is directed to sequences relating either to the entire lactoferrin molecule, or to the lactoferrin peptides belonging to a fragment of the N-lobe (see attached Exhibit A, by way of explanation). Exhibit A shows a

modelling of human lactoferrin, and illustrates that the peptides of the present invention are from the N-lobe of the human lactoferrin protein.

Applicants assert further that that the properties of the peptide sequences in the C-lobe and the N-lobe are significantly different. The N-lobe of the lactoferrin molecule contains positively charged surface structures, which possess biological activities i.e. microbicidal activity, binding to LPS, heparin, and heparansulphate, anti-inflammatory activity). These properties are not present in the C-lobe or in peptides from the C-lobe. Thus, the biological activity of the lactoferrin molecule is greatly determined by the interaction of the charged regions in the N-lobe.

Applicants 'arguments have not been found persuasive because the applicants are discussing limitations that are not present in the claims and are only available via "Exhibit A and by way of explanation". The claims of the present application are silent with regards to the so-called N- and C-terminal lobes of lactoferrin. In fact the examiner would like to submit that there is no discussion of so-called N- and C-terminal lobes of lactoferrin in the claims or the specification of the present application. Applicants have provided arguments that have no bases or support in the presently filed application. There is no indication that the applicants' invention is the use of any particular segment of lactoferrin since there is no information with regards to the amino acid sequence of the lactoferrin polypeptide used in the method of the invention of the present application.

It must also be noted that Reuban et al. clearly state that the polypeptide of their invention includes the mature form (Page 4, section 0031, line 1) and that by

demonstrating a "functional activity" is meant, a polypeptide capable of displaying one or more known functional activities associated with the full length (complete) protein of the invention and such functional activities include biological activity (Page 4, section 0033, lines 1-5).

Conclusion

No claims are allowed

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JON WEBER
SUPERVISORY PATENT EXAMINER

Robert B. Mondesi
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07-11-05